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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,634	04/05/2007	Mitchell C. Sanders	ETH5160USPCT [14972]	4673
25570 7590 04/28/2010 ROBERTS MLOTKOWSKI SAFRAN & COLE, P.C. Intellectual Property Department P.O. Box 10064 MCLEAN, VA 22102-8064			EXAMINER SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1657	
			NOTIFICATION DATE	DELIVERY MODE
			04/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/576,634	Applicant(s) SANDERS ET AL.	
	Examiner BIN SHEN	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Petition response</u> . |

DETAILED ACTION

Status of the Claims

Claims 1-15 are presented for examination on the merits.

Withdrawal of Rejection:

In view of amended claims and applicant's argument, the rejection under 35 USC, 112-2nd paragraph, and the rejection under 35 USC, 102(a) over Sanders, 102(b) over Asai, and Kulisek, and the rejection under 35 USC, 103(a) over Kulisek and Graham are hereby withdrawn.

The amendments to Drawings and Specification are accepted.

New rejections due to amendment to the claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: claim 1 lacks a correlating step to accomplish the preamble of the claim.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 8, 9, 11, 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf (1996).

Wolf teaches a method for detecting of proteolytic microorganisms from mixed populations using a Remazol Brilliant Blue R (CAS# 2580-78-1 same as Reactive blue No. 19, see attached SnagIt FDA approval Doc) labeled casein (casein-RBB, gelatin-RBB, collagen-RBB, dye-labeled substrates) for proteinase activity (page 339, left column, 1st paragraph, page 340, left column, 1st full paragraph, and Fig. 5 on page 341).

Therefore, Wolf teaches a method (**Claims 1**) for detecting proteolytic microorganisms (page 341, Fig. 5) by **a)** exposing an casein-RBB (in agar plate, page 340, left column, 1st full paragraph) to a sample of mixed microbial (page 340, right column, line 1-4) ; and **b)** detecting cleaving of the peptide that results in clearing of blue agar plate (page 341, Fig. 5, a visible color change); wherein the substrate is specifically cleaved by proteinase produced by *Verticillium lecanii*, etc. (page 341, Fig. 5 legend, read as microorganism); wherein the dye is a remazol dye (Remazol Brilliant Blue) approved by FDA; the dye Remazol Brilliant Blue is covalently bonded to the peptides (page 339, left column, 2nd paragraph, line 5, **Claim 2**); wherein the modification includes hydrolysis of a peptide bond and results in a portion of the peptide detaching from the substrate (proteolytic activity of microorganism, page 341, left column, lines 2-3, lines 11-12, **Claim 3**); wherein the dye is Remazol Brilliant Blue: a reactive fiber dye (page 338, left column, 2nd paragraph, lines 2-3, **Claim 5**); wherein the visible color change is a loss of blue color in the agar plate (page 341, Fig. 5, **Claim 6**); the peptide substrate is coupled into agar plate as solid support (**Claim 8**, agarose read as resin- **Claim 11**, page 339, left column, 1st paragraph); wherein the cleavage of the substrate results in a hue of the agar plate becoming more visible (page 341, fig. 5, **Claim 9**); and the sample tested is a well of microplate/agar plate (because the mixture of microbial population is added to the agar plate wells, page 340, right column, line 1-2,

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Claim 12); wherein the cleavage of the substrate inherently results in the migration of the cleaved portion of the peptide that resulting in the clearing of the blue agar plate (page 341, Fig. 5, **Claim 13**), therefore the agar plate (read as resin) is considered the collector (**Claim 14**); the method identifies protease from bacteria *Verticillium lecanii*, etc., (page 341, Fig. 5 **Claim 15**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 7, 8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wolf and Sanders (WO03/063693).

Wolf teaches what is above as applied to claims 1, 8.

Wolf does not teach the substrate listed in claim 4, the substrate is further includes a second colorimetric component that is dissimilar to the first colorimetric component, the peptide is covalently attached to the solid support.

Sanders teaches a method for detecting the modification of a peptide substrate by exposing an unmodified dye (for example, **two different dyes**: edans (5-((2-aminoethyl) amino)naphthalene-1-sulfonic acid and dabcy1 994-(4-(dimethylamino)phenyl)azo)benzoic acid see page 43, , **Claim 7**) labeled peptides (peptide substrates PAPA1/PALA1/PAGA1, page 42, example 13, and peptide substrate PAPA1 has the same sequence as SEQ ID NO:2 of the instant application, **Claim 4**) substrate on a solid support: wound dressing (page 4 lines 1-3, such as a wound dressing-page 26, 4th full paragraph, **Claim 10**) to a wound sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Wolf by substituting substrate-casein/collagen/gelatin with other peptide sequence such as SEQ ID NO:2 of the instant application and label it with two dyes

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for the detection of the specific microorganism producing the protease that cleave their specific substrate because Wolf teaches the detection of the proteolytic microorganisms with labeled substrate. One would have been motivated to make the modification because Wolf et al. specifically described a loss of color for detection of proteolytic microorganisms, and would reasonably have expected success in view of Sanders' teachings because they both use chromogenic assay in bacteria detection.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Maintenance of Rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3, 7, 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-3, 7-9 of copending Application No. 12139294. Although the conflicting claims are not identical, they are not patentably distinct from each other because same method of fluorescent two-dimensional differential in-gel electrophoresis is claimed to identifying a protein/expression profile regulating a cell phenotype.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The double patenting rejection maintained until a terminal disclaimer is filed and approved.

Applicant's arguments are moot in view of the new art rejections necessitated by the amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claim is allowed.

Art of record: Wang (2003 Feb) teaches labeling of peptide with vinyl sulfones as probe for cysteine protease assay (page 738, Scheme 1).

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Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen

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/Karen Cochrane Carlson/

Primary Examiner, Art Unit 1656